K123642

510(k) Summary

MAR 29 2013

510(k) Owner

Niveus Medical, Inc.
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Contact

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Date Prepared November 21, 2012

Device Name

Trade Name: Muscle Stimulation System 110
Powered Muscle Stimulator
Classification Name: Powered Muscle Stimulator
21 CFR 890.5850 (Product Code IPF)

Predicate Devices

Bio-Medical Research, Ltd.'s Neurotech Kneehab XP, Type 411 (K083105)
Koalaty Products, Inc.'s Twin Stim TENS/EMS Unit (K080661)
CEC Electronica SRL's Combi 8 Max (K070888)

Device Description

The Muscle Stimulation System 110 is a portable, externally-powered device which provides electrical stimulation to the quadriceps using constant current pulses. The device is a Powered Muscle Stimulator per 21 CFR § 890.5850 (Product Code: IPF). Pulses are delivered via six independently controlled stimulation channels (3 per leg) and are provided to the patient via electrodes integrated into disposable Stimulation Array Pads. An Interconnect Cable allows for communication between the System Controller and Stimulation Array Pads.

The major components of the system consist of a Controller, an Interconnect Cable, a pair of disposable Stimulation Array Pads configured for application to the quadriceps of a patient, a Power Cord, and instructions for use.

Indications for Use

The Muscle Stimulation System 110 is indicated for:

- Maintaining or increasing range of motion of the

knee joint
- Prevention or retardation of disuse atrophy in the quadriceps
- Muscle re-education of the quadriceps
- Relaxation of muscle spasms
- Increasing local blood circulation

Technological Characteristics The technological characteristics of the subject device are substantially equivalent to the predicate devices and have been compared to the predicates for the following characteristics listed in FDA's June 1999 guidance for powered muscle stimulators: output waveforms, basic unit characteristics, output specifications, accessories, and software/firmware/microprocessor control.

Performance Data Performance data from usability testing, electrical safety and compatibility testing, software and hardware validations, packaging and transit validation, and shelf-life and biocompatibility evaluations demonstrate that the device performs as intended and is substantially equivalent to the predicate devices.

Conclusion Based on the testing data provided, the Muscle Stimulation System 110 is as safe and effective and functions in substantially equivalent manner to the predicate devices identified above. To minimize potential hazards to the patient, the device has been specified, manufactured, and the design verified based on Good Manufacturing Practices and the Quality System Regulations, with risk management applied throughout the process. The system conforms to UL and IEC electrical safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 29, 2013

Niveus Medical, INC.
% Ms. Cindy Domecus
1171 Barroilhet Drive
Hillsborough, CA 94010

Re: K123642
Trade/Device Name: Muscle Stimulation System 110
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: February 11, 2013
Received: February 14, 2013

Dear Ms. Domecus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123642

Device Name: **Muscle Stimulation System 110**

Indications for Use:

The Niveus Medical Muscle Stimulation System 110 is indicated for:

- Maintaining or increasing range of motion of the knee joint
- Prevention or retardation of disuse atrophy in the quadriceps
- Muscle re-education of the quadriceps
- Relaxation of muscle spasms
- Increasing local blood circulation

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
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Division of Neurological and
Physical Medicine Devices
510(k) Number: K123642